REMARKS

By this paper, claims 14 and 24 have been amended. Claims 34-38 have been canceled. Claims 14-33 remain pending of which claims 29-33 have been withdrawn.

Based on the Examiner's comments in the Office action mailed on June 7, 2004 and in the Office action mailed on August 6, 2003, the amendments made to the claims in the present paper should overcome the Examiner's objections.

It is believed that the only outstanding objection in relation to claims 14-28 is the rejection under 35 U.S.C. § 112, first paragraph.

The Examiner's concerns in relation to claims 14-28 relate to the term "preventing." The Examiner has stated that the instant specification does not provide support for "preventing" cataract or after-cataract. The Examiner states there is no support in the specification to demonstrate the prevention of cataract or after-cataract by using TGFβ inhibitors. The Examiner has also stated that the specification fails to set forth a representative number of TGFβ inhibitors which would be capable of prevention or control of cataract or after-cataract. The Examiner has stated that since compound structure and activity for such pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all TGFβ inhibitors which would be capable of controlling or treating cataract or after-cataract.

As discussed below, we submit the specification does provide support for the prevention of cataract or after-cataract by using TGFβ inhibitors. Nevertheless, to address the Examiner's concerns, claims 14 and 24 have been amended by replacing the words "preventing or controlling" with "inhibiting." We note the Examiner's comment in the Office action mailed on August 6, 2003 that "The support in the specification shows the treatment of cataract induced by

the growth factor by using the claimed compound, a growth factor antagonist." Accordingly, this amendment should address the Examiner's concerns.

As mentioned above, we nevertheless submit that the specification does provide support demonstrating the prevention of cataract or after-cataract by using TGFβ inhibitors. The specification clearly describes the prevention of cataract or after-cataract, for example, in the Disclosure of the Invention at page 1, lines 30-34, and suitable inhibitors of TGFβ for use in the method of the invention are described at page 2, lines 4-12. In addition, Example 2 describes a study which demonstrates the use of a TGFβ inhibitor to prevent cataract or after-cataract like changes in lens cells. In Example 2, a TGFβ antibody (a TGFβ inhibitor) was used to inhibit cataract and after-cataract like changes in lens explants cultured with TGFβ. The effects of the TGFβ antibody (a pan-specific polyclonal IgG antibody against TGFβ) were compared with a control in which the inhibitor was replaced with non-immune IgG. Figure 1 shows phase contrast micrographs of the lens epithelial explants cultured with TGFβ and non-immune IgG (Figures 1A, B) or with TGFβ and the TGFβ antibody (Figures 1C, D). As noted at page 14, lines 21-32, the micrographs show that TGFβ induces extensive elongation of cells, and subsequently many cells are lost exposing regions of capsule which show wrinkles. As indicated in Example 1 at page 13, lines 20-24, these changes are characteristically reported to occur during the formation of various types of cataracts (references 13-15) and after-cataract (reference 16). As noted at page 15, lines 3-7, the TGFβ antibody in Example 2 "completely blocked" these changes (see also page 14, line 28-30). Accordingly, Example 2 demonstrates the use of a TGFβ inhibitor to prevent TGFβ induced cataract or after-cataract formation.

As indicated in the specification, any inhibitor of TGFβ may be used in the method of the present invention. Representative examples of TGFβ inhibitors which can be used are referred to

throughout the specification, including page 2, lines 4-12. Specific examples of TGFβ inhibitors which may be used are referred to in the Examples.

We submit that a person skilled in the art can readily determine whether a compound is an inhibitor of TGFβ.

TGFβ (transforming growth factor β) has been known for some time and is extensively described in the literature. Numerous compounds capable of inhibiting TGFβ are known and are described in the literature.

The activity of a substance to inhibit TGFβ can be readily determined by using a standard bioassay for TGFβ. A standard bioassay for TGFβ activity before the priority date of this application, and today, is the mink lung test. This test involves the study of the ability of a given TGFβ-containing sample to inhibit cell proliferation in mink lung epithelial cells. This bioassay is described in numerous documents (including Danielpour et al., 1989; Lucas et al., 1991). This bioassay has for example been used to determine that various antibodies are effective as TGFβ inhibitors (Danielpour et al., 1989; Lucas et al. 1991) and to demonstrate that α_2-macroglobulin (Cheifitz et al., 1990; Danielpour and Sporn, 1990) and decorin (Yamaguchi Y., et al., 1990; reference 18 on page 21 of the specification) act as TGFβ inhibitors.

A copy of Danielpour et al., 1980 was filed with the Information Disclosure Citation filed on November 9, 2001. A copy of Lucas et al., 1991 and Cheifitz et al., 1990 have been submitted herewith in an Information Disclosure Statement.

We submit a person skilled in the art can readily determine whether a particular compound is an inhibitor of TGFβ, and therefore one of ordinary skill in the art would not be burdened with undue experimentation to determine whether a compound is a TGFβ inhibitor.

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully requests that the application be reconsidered, the claims allowed and the application passed to issue.

Respectfully submitted,

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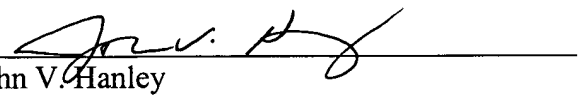
By: 
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